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| APPLICATION NO.              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.  |
|------------------------------|-------------|----------------------|---------------------|-------------------|
| 09/889,645                   | 01/24/2002  | Anne Gillian Welch   | 9013.31             | 8639              |
| 20792                        | 7590        | 10/13/2006           |                     | EXAMINER          |
| MYERS BIGEL SIBLEY & SAJOVEC |             |                      |                     | BOESEN, AGNIESZKA |
| PO BOX 37428                 |             |                      | ART UNIT            | PAPER NUMBER      |
| RALEIGH, NC 27627            |             |                      | 1648                |                   |

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/889,645             | WELCH ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Agnieszka Boesen       | 1648                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 18 September 2006.
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1,3,6-19,23 and 25-29 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1,3,6-19,25-27 and 29 is/are rejected.
- 7)  Claim(s) 23 and 28 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_

### **DETAILED ACTION**

Upon further consideration the finality of the previous Office Action of July 5, 2006 is withdrawn. Prosecution is reopened to make the following rejections. Any inconvenience is regretted.

The Amendment filed September 18, 2006 is acknowledged and entered. Claims 1, 3, 17, 18, 26, and 27 have been amended. Claim 29 has been added. Claims 1, 3, 6-19, 23, and 25-29 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Objections***

Claims 23 and 28 are objected to because the claims depend from rejected claim 1.

#### ***Claim Rejections - 35 USC § 112***

Rejection of claims 1, 17, 18, 26, and 27 are under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **maintained** for reasons of record (see Office action of July 5, 2006). Applicant failed to address the rejection in the Remarks of September 18, 2006.

Rejection of claims 1, 17, 18, 26, and 27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **maintained** for reasons of record (see Office action of July 5, 2006). Applicant failed to address the rejection in the Remarks of September 18, 2006.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 8, 9, 14, 16, 17, 18, 26 and 27 under 35 U.S.C. 102(b) as being anticipated by Nebe (WO 96/05846, IDS Paper No. 1) is withdrawn in view of Applicants' amendments to the claims.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 7-19, and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Nebe (WO 96/05846, IDS Paper No. 1), Omar et al. (U.S. Pat. No. 5,696,236, IDS Paper No. 1) and Savage et al. (EP 0 798 003 A2, IDS Paper No. 1) is withdrawn in view of Applicants' amendments to the claims. However, upon further consideration, in view of the amendments to the claims a new ground(s) of rejection is made in view of newly found prior art references.

**Claims 1, 3, 6-19, 23, and 25-7, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostreicher et al. (GB 2 045 828 A, 1980) in view of Nebe (WO 96/05846, IDS Paper No. 1) as evidenced by Encyclopedia Britannica ([britanica.com/eb/article-9030299/diatomaceous-earth](http://britanica.com/eb/article-9030299/diatomaceous-earth), access 10/5/2006).**

Claims are drawn to a method of removal of abnormal infective prion proteins from an aqueous liquid comprising passing the liquid through a depth filter formed of a matrix comprising a cellulose binder and kieselguhr or perlite particles having a pore size providing retention less than 6  $\mu\text{m}$ . The method is carried out in the absence of cationic or anionic charged material at a pH in the range 4 to 10. The removal of the abnormal prion proteins is achieved to an extent of at least  $10^{2.5}$  factor. The filter is a single use filter.

For the purposes of the current rejection it is noted that “kieselguhr” is the same as “diatomaceous earth” as evidenced by Encyclopedia Britannica.

Ostreicher teaches a method of removal of submicron contaminants such as bacteria and viruses from aqueous liquids such as biological liquids using a filter formed of self-bonding matrix (binder) comprising cellulose, diatomaceous earth and perlite particles (see the entire document, particularly claims 1, 2, 8-11, 19, and 20, page 1, lines 20-37, page 2, lines 14-19, and Example V, page 10, lines 47-53). Because Ostreicher teaches a method of removal of submicron contaminants (and submicron means a size from 1  $\mu\text{m}$  to 0.1 or less), Ostreicher’s method automatically provides retention of particles less than 6  $\mu\text{m}$ . Ostreicher teaches that it is desirable to wholly remove the organic charge modifier resin from the filter construction in systems where even low levels of organic extractables are unacceptable. Thus Ostreicher teaches that his method can be carried out in the absence of cationic or anionic charged material (see page 2, lines 13-15). Ostreicher teaches various pH, such as 5.5, 7.5 – 8.5 (see Example V).

Although Ostreicher teaches removal of submicron contaminants such as bacteria and viruses from aqueous liquids, Ostreicher does not expressly mention prion proteins. However, because prion proteins are submicron contaminants of a biological sample and because Nebe (WO 96/05846, IDS Paper No. 1) teaches removal of prion form solution using ultramembrane filters, it would have been obvious to use Ostreicher’s filter to remove prion proteins. The person of ordinary skill in the art would have been motivated to use Ostreicher’s filter to remove Nebe’s prion proteins from biological liquids because Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 microns to 0.2 microns (see page 10). Nebe also teaches that using filters providing retention from 2.0 microns to 0.2

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microns removes prion protein by factor of  $10^{4.67}$  (see page 14). One of ordinary skill in the art would have had a reasonable expectation of success to use Ostreiche's filter to remove Nebe's prion proteins because Ostreiche's filter is capable of removing submicron contaminants.

The claims as written are not limited to the use of only one type of filter. The method steps "comprise" the use of a depth filter, which is known in the art to be a prefilter, the claims can include other filtration steps to achieve the purpose of removing the prion protein from the sample. The transitional term "comprising," which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*AB*

Agnieszka Boesen, Ph.D.

*10/6/06*

*Stacy B. Chen 10/6/06*  
STACY B. CHEN  
PRIMARY EXAMINER